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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,378	06/23/2003	David Farrow	SMB-004	7906

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EXAMINER	
SKOWRONEK, KARLHEINZ R	
ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 05/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/601,378	FARROW, DAVID	
	Examiner	Art Unit	
	Karlheinz R. Skowronek	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *9-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☒ Claim(s) *6-8* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 June 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *(2 sheets)*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of the invention of Group I (claims1-8) in the reply filed on 02 February 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 9-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 02 February 2006.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on 17 May 2004 and 07 November 2005 were filed after the mailing date of the application (10/601378) on 23 June 2003. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered by the examiner.

Specification/Claim Objections

4. Claim 6 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is

required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 6 does not further limit claim 4 from which it depends.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 7-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

7. Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in *Ex parte* Forman, 230 USPQ 546 (BPIA 1986) and reiterated by the courts in *In re* Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of the experimentation necessary, (2) the amount or the direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The Board also stated that although the level of skill in molecular Biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for *prima facie* case are discussed below.

8. In the instant case, claim 7 is drawn to a truncated CD4 glycoprotein. The specification recites truncated CD4 glycoprotein in "For example, the reagent solution can contain truncated CD4 glycoprotein particles 38 (p.8, [0053])". However, the specification fails to provide guidance to the precise truncated CD4 glycoprotein moiety the applicant considers the truncated CD4 glycoprotein with which one of ordinary skill in the art could practice the invention. It would require undue experimentation to determine a truncated CD4 glycoprotein moiety with which to practice applicant's invention. The CD4 glycoprotein is transmembrane protein of approximately 433 amino acids and composed of multiple domains. (Sweet, RW. "CD4" 2002. *In* Wiley Encyclopedia of Molecular Medicine, Volumes 1-5 Edited and published by: John Wiley & Sons, Inc.) A vast plurality of truncated CD4 proteins could be produced by one skilled in the art, but would require additional experimentation to determine suitable species with which to practice the invention. Thus, the function of a truncated CD4 in the instant invention is unpredictable without knowledge of precise CD4 truncation moiety or moieties and sources of truncated CD4 with which to practice the instant invention. What domain or domains of the CD4 extracellular region would be sufficient for interaction with HIV AND provide an increase in HIV particle size suitable to sequester the HIV-CD4? The specification fails to provide working examples of suitable CD4 truncations. Further, the specification does not provide guidance or working

examples of the source of truncated CD4 glycoprotein. For example, can truncated CD4 be produced recombinantly and still be used to practice the invention? Or, what is the glycosylation state of truncated used in the practice of the instant invention? Would HIV particles bind non-glycosylated CD4? Therefore, an undue experimentation burden is required to obtain truncated CD4 glycoprotein.

Claim 8 is drawn to microinjected molded plastic used to perform the filtering. However, the specification fails to provide details regarding the filtering aperture limits required to produce a microinjected molded plastic capable of filtering analyte particles. It would require undue experimentation to produce a working filtering device of microinjected molded plastic with filtering apertures. The filtering aperture specific to claim 8 has critical implicit requirements, which without guidance from the specification require undue experimentation. For instance, the aperture has the implicit requirement of being sized such that a native virus, for example, is capable of passing through the aperture, but a virus-reagent complex is not capable of passing through the aperture. Since the specification gives neither working example nor specific description of filtering aperture limits, an undue amount of experimentation would be required to develop a filtering aperture capable of separating analyte particle from analyte particle-reagent complex. One of ordinary skill in the art may be able to develop such a filtering aperture given enough time, however the amount of experimentation makes development of such a filter aperture unpredictable without the necessary guidance from the specification. Additionally, one cannot practice the invention of claim 8 without the

correct aperture. Therefore an undue amount of experimentation is required to perform the filtering of claim 8.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-3 and 5 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Coller et al. (US PAT 3,872,225).

11. Claims 1-3 and 5 are directed to detecting a particle isolated from a fluid (claim 1 limitation), a biological fluid (claim 2 limitation) or blood (claim 3 limitation) where the particle may be a virus (claim 5 limitation) or protein. That particle is separated from larger particles by filtration (claim 1), complexed with a reagent (claim 1), the reagent particle complex separated by filtration from particles that are smaller (claim 1) and finally the fluid tested for the presence of the reagent-particle complex (claim1).

12. In Coller et al., the Australia antigen, which may be a virus (col1, lines 27-29 and 37-39) is isolated from human blood plasma (col 3, lines 61-65; col 4, lines 1-30) by passing fluid containing the Australia antigen over a gel filtration column (col 4, lines 40-46) This step separates the antigen from particles that are larger than it. The antigen is then conjugated (complexed) to a compound containing an Iodine radioisotope (col 6, lines 5-15) and then filtered to remove particle that are smaller than the Australia

antigen-isotope complex (col 6, lines 42-69). Finally, the isotope-antigen complex is tested to determine the presence of the antigen in the fluid (col 7, lines 1-8). Thus, Coller et al. clearly anticipates the instantly claimed invention of claims 1-3 and 5.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 4 and 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coller et al. as applied to claims 1-3 and 5 above, further in view of Motomura et al. (US PAT 5,667,684), and further in view of King et al. (US PGPUB 20010008760).

15. Claims 4 and 6 are directed to a method of removing HIV from a fluid by filtering.

16. Coller et al describe the separation of particle larger than the Australia antigen and particles smaller than the Australia antigen from the Australia antigen. Coller et al. also describe the labeling of the Australia antigen to aid in its detection (see above). Coller et al do not teach the separation of HIV from particle within fluid or the use of CD4, but suggest or motivates the use in " detecting the presence of such an antigen or its antibody if it should happen to be present in other biological fluids and not merely human sera as for example, the body fluids of lower animals tissue culture fluids water supplies, etc. (col. 16, lines64-68)"

17. In Motomura et al., HIV is filtered through a medium that has been modified such that it binds and immobilizes HIV particles (claims 4 and 6), thereby separating HIV particles from the fluid being filtered. Motomura et al. describes a material that is "capable of removing the HIV and its related substances from blood and plasma (col. 11, lines 24-25)" and "selectively remove HIV and its related substances from the liquid such as blood that contain a variety of proteins (col. 3, lines 30-32). The material is used in a method described by Motomura et al. as:

> "When the material for removing the HIV and its related substance may be in the form of a porous filter or a bead. Preferably the porous filter has an average pore diameter of from 0.1 to 1.0 μm, and has the sulfate group on its pore surface substantially in the form of a salt, it may be used as a horizontal filter in the filtration of blood to thereby accomplish plasma separation simultaneously with the removal by adsorption of the HIV and its related substances. Use of such filter also enables a convenient preparation of the HIV removing system. (Col.7, lines 58-67)"

However, Motomura et al. do not describe the use of truncated CD4 to detect HIV, but suggests or motivates that, "Removal of HIV, gp120 and the like from the body fluid of the patient suffering from HIV blood conditions should result in the reduction of the virus load and prevention of the virus spread, and hence, in the improvement of the QOL (quality of the life) of the patient and suppression of the disease progress. (Col. 3, lines 39-45)"

18. King et al. describe the use of CD4 "coupled to a surface and then used to capture cells expressing the viral antigen (pg 6, [0054])"(claim 7 limitation). The surface of King et al. includes magnetic particles [0058]. One of ordinary skill in the art will recognize that the method of King et al. will also result in the capture of viral particles expressing the antigen. Thus the method of King et al is capable of separating viral particles from other particles in a fluid. King et al. also describe the use of CD4 in

detecting HIV by conjugating CD4 to a fluorescent moiety, FITC, and using flow cytometry to detect the FITC [0057], and suggest or motivates the "need for the present invention based upon the limitations posed by current screening and confirmatory test protocols which are still mainly dependent upon host immune response to HIV infection by antibody production [0034]" and "infected cells can be detected and separated from uninfected cells [003]".

19. Thus it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice the method of Coller et al, with the material of Motomura et al. and the CD4 of King et al. thus resulting in the practice of the instantly claimed invention with a reasonable expectation of success.

No claims allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karlheinz R. Skowronek whose telephone number is (571) 272-9047. The examiner can normally be reached on Mon-Fri 8:00am-5:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Ardin H. Marschel 4/27/06
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SUPERVISORY PATENT EXAMINER